

WHAT IS CLAIMED IS:

1. An analyzing method comprising analyzing an amount and/or function of pancreatic β -cells, using a biological sample that has incorporated therein a recombinant expression vector in which a reporter gene is placed under the control of a promoter region of a pancreatic β -cell-specific gene.

2. An analyzing method as set forth in claim 1, comprising:

a transforming step of introducing the recombinant expression vector into the biological sample;

a detecting step of detecting a product of the reporter gene expressed in the biological sample to which the recombinant expression vector was introduced in the transforming step; and

an analyzing step of analyzing an amount and/or function of pancreatic β -cells based on a result of detection performed in the detecting step.

3. An analyzing method as set forth in claim 2, wherein, when the reporter gene is a gene that encodes an extracellular secreted product, the detecting step further comprises:

an extracting step of extracting an extract from the

biological sample to which the recombinant expression vector was introduced in the transforming step; and

an extract detecting step of detecting the product of the reporter gene included in the extract obtained in the extracting step.

4. An analyzing method as set forth in any one of claims 1 through 3, further comprising an expression vector constructing step of constructing the recombinant expression vector.

5. An analyzing method as set forth in any one of claims 1 through 4, wherein the recombinant expression vector includes an enhancer region.

6. An analyzing method as set forth in any one of claims 1 through 5, wherein the pancreatic β -cell-specific gene comprises at least one gene selected from the group consisting of pdx-1 gene, NeuroD1 gene, Nkx2.2 gene, Nkx6.1 gene, Pax4 gene, Pax6 gene, insulin gene, glucokinase gene, GLUT2 gene, and amylin gene.

7. An expression vector in which a reporter gene is placed under the control of a promoter region of a pancreatic β -cell-specific gene.

8. A transformant to which the recombinant expression vector set forth in claim 7 is introduced.

9. An analyzing kit for performing an analyzing method set forth in any one of claims 1 through 6.

10. An analyzing kit as set forth in claim 9, including at least one substance selected from the group consisting of:

(a) a recombinant expression vector in which a reporter gene is placed under the control of a promoter region of a pancreatic β -cell-specific gene;

(b) a transformant to which the recombinant expression vector of (a) is introduced;

(c) a reagent for introducing the recombinant expression vector of (a) into an animal cell; and

(d) a reagent for detecting a product of the reporter gene of (a).

11. A screening method for screening for a candidate substance of an anti-diabetic drug, comprising:

an administering step of administering a test substance to a biological sample that has incorporated therein a recombinant expression vector in which a reporter gene that encodes an extracellular secreted

product is placed under the control of a promoter region of a pancreatic β -cell-specific gene;

a detecting step of detecting the product of the reporter gene that is expressed in the biological sample that was administered with the test substance in the administering step;

an analyzing step of analyzing an amount and/or function of pancreatic β -cells based on a result of detection in the detecting step; and

a determining step of determining that the test substance is a candidate substance of an anti-diabetic drug, when a result of analysis in the analyzing step indicates there is improvement in the amount and/or function of the pancreatic β -cells.

12. A determining method for determining whether administration of a test substance has treated or relieved diabetes mellitus, comprising:

an administering step of administering a test substance to a biological sample that has incorporated therein a recombinant expression vector in which a reporter gene that encodes an extracellular secreted product is placed under the control of a promoter region of a pancreatic β -cell-specific gene;

a detecting step of detecting the product of the

reporter gene that is expressed in the biological sample that was administered with the test substance;

an analyzing step of analyzing an amount and/or function of pancreatic β -cells based on a result of detection performed in the detecting step; and

a determining step of determining that the administration of the test substance has treated or relieved diabetes mellitus, when a result of analysis in the analyzing step indicates there is improvement in the amount and/or function of the pancreatic β -cells.